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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,039	02/08/2001	Gregory S. Friedrichs	AM100143	4428

7590 10/21/2002

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EXAMINER	
MURPHY, JOSEPH F	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 10/21/2002 6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/779,039	Applicant(s) FRIEDRICHS ET AL.	
	Examiner Joseph F Murphy	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6,12 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2, 3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Species etanercept in Paper No. 5, 8/7/2002 is acknowledged. The traversal is on the ground(s) that the compounds etanercept and p55TNFR:Fc are so related that a search for art on the one compound would lead to art on the other, and thus there is no additional burden to search. This is not found persuasive because while etanercept is derived from the p75 soluble TNF receptor, p55TNFR:Fc is derived from the p55 soluble TNF receptor. Contrary to applicants' assertion that any search of the prior art in regard to etanercept will reveal whether any prior art exists as to p55TNFR:Fc, a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-17 are pending. Claims 6, 12 and 17 are withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 1-5, 7-11, 13-16 are under consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 9-11, 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Deswal et al. (1999).

Deswal et al. teaches the selection of patients in need of therapy for an ischemic event in a mammal, and the administration of a TNF antagonist to treat said mammal. In this study Eighteen NYHA class III heart failure patients were randomized into a double-blind dose-escalation study to examine the safety and potential efficacy of etanercept, a specific TNF antagonist (Enbrel) (Deswal at 3224). Of the patients enrolled in the study, 4 had ischemic heart disease (Ibid. at 3225, Table I), thus claims 1, 2 are anticipated. Etanercept contains 2 molecules of the extracellular domain of sTNFR2 linked to the Fc portion of the IgG1 molecule (Ibid. at 3225), thus claims 3-5 are anticipated. Myocardial infarction is an ischemic event, thus claims 13-16 are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-11, 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deswal et al. (1999) in view of Ferrari et al. (1999).

Deswal et al. teaches the selection of patients in need of therapy for an ischemic event in a mammal, and the administration of a TNF antagonist to treat said mammal. In this study Eighteen NYHA class III heart failure patients were randomized into a double-blind dose-escalation study to examine the safety and potential efficacy of etanercept, a specific TNF antagonist (Enbrel) (Deswal at 3224). Of the patients enrolled in the study, 4 had ischemic heart disease (Ibid. at 3225, Table I). Etanercept contains 2 molecules of the extracellular domain of sTNFR2 linked to the Fc portion of the IgG1 molecule (Ibid. at 3225). Myocardial infarction is an ischemic event. Deswal et al. does not teach a method of inhibiting reperfusion injury in a mammal in need of treatment thereof with a TNF antagonist. Ferrari et al. teaches that there is increasing evidence that cytokines in general and tumour necrosis factor (TNF) in particular play an important role in cardiovascular disease. Increased levels of TNF have been implicated in the pathophysiology of ischemia-reperfusion injury, myocarditis, cardiac allograft and also in the progression of congestive heart failure (Ferrari at 99). Thus, it would have been obvious to one of skill in the art at the time the invention was made to practice a method of treating mammals in need of treatment for an ischemic event, myocardial infarction or reperfusion injury, with a TNF antagonist such as etanercept. The motivation is provided in Ferrari et al. who teaches that the extent of the increase in TNF levels is related to the severity of the syndrome, and that the

cytokines contribute to the severity and progression of congestive heart failure (Ibid at 99), and that treatment with anticytokine therapy is safe (Ibid. at 102).

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
October 10, 2002